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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/934, 254 09/19/97 THOMAS

T 18383ZYXWVU

HM22/1012

EXAMINER

LEOPOLD PRESSER
SCULLY SCOTT MURPHY & PRESSER
400 GARDEN CITY PLAZA
GARDEN CITY NY 11530

MCELWAIN, E

ART UNIT	PAPER NUMBER
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1649

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DATE MAILED:

10/12/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
08/934,254

Applicant(s)

Thomas

Examiner

Elizabeth McElwain

Group Art Unit

1649 Responsive to communication(s) filed on Jul 28, 1999. This action is **FINAL**. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims Claim(s) 1-46 is/are pending in the application.Of the above, claim(s) 36-46 is/are withdrawn from consideration. Claim(s) 1-6, 9, 10, and 18-21 is/are allowed. Claim(s) 7, 8, 11-17, and 22-35 is/are rejected. Claim(s) _____ is/are objected to. Claims _____ are subject to restriction or election requirement.**Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on _____ is/are objected to by the Examiner. The proposed drawing correction, filed on _____ is approved disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119** Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). All Some* None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) _____. received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)** Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152**--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---**

Applicant's election with traverse of Group I, claims 1-35 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the inventions were not shown to be independent and distinct. This is not found persuasive because it is not a requirement that the inventions are shown to be both independent and distinct, as applicants have asserted.

5 The reasons set forth by the Examiner in the restriction requirement are valid and proper, and it is maintained that it would be a burden to the Examiner to examine all of the claimed inventions.

The requirement is still deemed proper and is therefore made final.

10 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15 Claims 11 and 22, and claim 23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite in the recitation of "seed termination signal", given that it is unclear what this is intended to mean.

20 Claim 22 is indefinite in the recitation of "a plant or progeny . . . which has been regenerated from the plant cell of . . .", since it is unclear how a progeny would be regenerated from said plant cell.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

5 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 8 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had 10 possession of the claimed invention. The claims are drawn to vectors that comprise specified regulatory sequences, including: a delta 6-desaturase, albumin, oleosin or helianthinin promoter, and a seed termination signal, which are not disclosed or described in the specification. And while the specification refers to copending applications as disclosing the albumin and oleosin promoters, as these are essential elements of the claims, they are improperly incorporated by reference. Thus 15 the claimed regulatory sequences are not adequately described in the specification by structural and physical characteristics.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states:

20 “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a 25 written description of the invention . . .”

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, and given the high level of unpredictability in this art, one skilled in the art would not have been in possession of all of the elements of the claims at the time this application was filed.

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Claims 7, 8, 11-17 and 24-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

10 Claims 7, 8 and 11 are drawn to vectors that comprise specified regulatory sequences, including: a delta 6-desaturase, albumin, oleosin or helianthinin promoter, and a seed termination signal, which are not disclosed or described in the specification. And while the specification refers to copending applications as disclosing the albumin and oleosin promoters, as these are essential elements of the claims, they are improperly incorporated by reference. Given the absence of
15 guidance in the specification for the obtention of the claimed regulatory sequences, the lack of working examples, and the unpredictability with regard to the structure of said sequences, it would require undue experimentation by one skilled in the art to make and use the claimed vector constructs.

20 In addition, claims 12-17 are drawn to transformation of cells, including animal cells, and claims 33-35 are drawn to a method of inducing or increasing GLA in an organism, which would include animals, that are transformed with the claimed vector constructs. However, there is no

disclosure in the specification with regard to how one would transform the animal cells, what type of animal cells, and how one would use these cells once they are transformed. In addition, there is no guidance with regard to making transformed organisms other than microbes or plants.

Therefore, given the lack of guidance in the specification, absence of working examples, and
5 the unpredictability with regard to transformation and expression of a gene in any animal cell and any organism, it would require undue experimentation by one skilled in the art to make and use the claimed transformed animal cells and organisms.

Furthermore, claims 24-35 are drawn to modifying the content of GLA in a cell or organism. However, the specification provides no examples of increasing GLA in any cell
10 types or organisms by transforming said cell or organism with the disclosed evening primrose delta 6-desaturase. De Luca teaches the unpredictability of modifying metabolic pathways in a plant (see the paragraph bridging the columns of page 225N and the last paragraph of page 228N). Given the lack of guidance in the specification, absence of working examples, and the unpredictability with regard to modifying metabolic pathways by transforming with a gene,
15 it would require undue experimentation by one skilled in the art to make and use the claimed invention.

The claims are deemed free of the prior art given that a gene encoding evening primrose delta 6-desaturase was not known or suggested in the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Tuesday through Friday from 7:30 AM to 5:00 PM. The examiner can also be reached on alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Elizabeth F. McElwain, Ph.D.
October 8, 1999

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600
Elizabeth F. McElwain